



DEPARTMENT OF HEALTH & HUMAN SERVICES

New York District

Food & Drug Administration
158-15 Liberty Avenue
Jamaica, NY 11433

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Roger E. Nasiff
President
Nasiff Associates, Inc.
841-1 County Route 37
Central Square, NY 13036

December 8, 2006

Ref: NYK-2007-05

Dear Mr. Nasiff:

During an inspection of your establishment located in Central Square, New York, on October 12 through 18, 2006, our investigator determined that your establishment manufactures the Cardio-Card Interpretation System I. Under section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 321(h), these products are devices because they are intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, or are intended to affect the structure or function of the body.

The inspection revealed that these devices are adulterated within the meaning of Section 501(h) of the Act, 21 U.S.C. § 351(h), in that the methods used in, or facilities or controls used for their manufacturing, packing, storage, or installation are not in conformance with the Current Good Manufacturing Practice (CGMP) requirements of the Quality System (QS) regulation found at Title 21, Code of Federal Regulations (C.F.R.), Part 820. These violations include, but are not limited to, the following:

1. Failure to document corrective and preventive actions, as required by 21 C.F.R. § 820.100(b). For example, your firm has not documented the nonconformity, the investigation of the cause of the nonconformity, or the analysis of quality data regarding the Cardio-Card Interpretation System I devices, including, but not limited to, serial numbers 1001, 1094 and 1157, which were returned to your firm and retested by your firm.
2. Failure to establish and maintain corrective and preventive action procedures that include an analysis of all quality data to identify existing and potential causes of nonconforming products, as required by 21 C.F.R. § 100(a)(1). For example, your firm's Product Failure Reporting Procedure does not identify all sources of quality data, such as: complaints, incoming inspection records, purchasing logs, returned product and customer notes.

3. Failure to implement the procedures for the acceptance or rejection of incoming product, including the documentation of acceptance or rejection, as required by 21 C.F.R. § 820.80(b). For example, your Quality Control Receiving Inspection Procedure is not followed in that Incoming Inspection Plan/Vendor History Cards are not completed.
4. Failure to document in-process acceptance activities, as required by 21 C.F.R. § 820.80(c). For example, there is no documentation of the required function test that is performed on the circuit boards during subassembly.
5. Failure to include in the Device History Records the dates of manufacture and the primary identification label used for each production unit, as required by 21 C.F.R. § 820.184(a) and (e).

You should take prompt action to correct the violations addressed in this letter. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties. Also, federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, premarket submissions for Class III devices to which the Quality System deficiencies are reasonably related will not be approved until the violations have been corrected. Requests for Certificates to Foreign Governments will not be granted until the violations related to the subject device have been corrected.

Please notify this office in writing, within fifteen (15) working days from the date you receive this letter, of the specific steps you have taken to correct the noted violations, including an explanation of how you plan to prevent these violations, or similar violations, from occurring again. Include documentation of the corrective action you have taken. If your planned corrections will occur over time, please indicate a timetable for implementation of those corrections. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

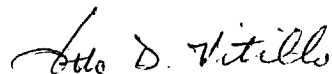
Your response should be sent to Laurence D. Daurio, Compliance Officer, New York District, Food & Drug Administration, 158-15 Liberty Avenue, Jamaica, NY 11433.

Nasiff Associates, Inc..

page 3

Finally, you should know that this letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and its regulations. The specific violations noted in this letter and in the Form FDA 483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your establishment's quality system. You are responsible for investigating and determining the causes of the violations identified by the FDA. You must also promptly initiate permanent corrective and preventive action on your Quality System.

Sincerely,

A handwritten signature in cursive script, reading "Otto D. Vitillo".

Otto D. Vitillo
District Director